## TCT-429

### Short- and intermediate- term clinical outcomes after implantation of everolimus-eluting bioresorbable scaffold in complex lesions : a prospective single-arm study - ABSORB Expand trial

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**Background:** Bioresorbable scaffold is a novel approach that provides transient vessel support with drug delivery capability without the long-term limitations of metallic drug-eluting stents. The everolimus-eluting bioresorbable scaffold (ABSORB; Abbott vascular, CA, USA) has been shown to be effective in the context of first-in-man trials including simple lesion(s). However, the effect of ABSORB implantation in more complex patients cannot be directly extrapolated from these findings. We sought to evaluate the impact of this novel technology on the short- and intermediate- term clinical outcomes in a real-life population with complex lesions.
**Methods:** Since September 1st 2013, our institution commenced the use of ABSORB scaffold in patients with complex lesions including a long lesion (>32mm in length), a calcified lesion, a bifurcation lesion and a large vessel with up to 4mm in diameter. Patients presenting with stable angina, unstable angina and non-ST elevation myocardial infarction were included. In total 300 patients presenting with de novo complex lesions will be treated exclusively with ABSORB scaffolds.
**Results:** Up to May 1, 2013, 137 patients were included in the study. In total 248 scaffolds were implanted, with a procedural success rate of 95%, in the lesions including 40 bifurcations and 11 chronic total occlusions. In 52 patients (53 lesions), more than one scaffold was implanted with overlap. An interim analysis of the population at one month revealed no MACE event except for one myocardial infarction. The enrolment is ongoing while the updated one-month and 6-month data on the occurrence of death, MI, repeat revascularization and scaffold thrombosis are currently being collected and will be presented at the time of the meeting. Survival information will be obtained from municipal civil registries.
**Conclusions:** The short-term and intermediate-term clinical safety and efficacy of the ABSORB scaffold in complex lesions will be presented at the meeting.

## TCT-430

### ABSORB everolimus-eluting bioresorbable vascular scaffold (BVS) implantation in daily clinical practice. A single center registry analysis

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**Background:** The ABSORBTM bioresorbable vascular scaffold (BVS) (Abbott Vascular, Santa Clara, CA, USA) is a resorbable polymeric scaffold that provides temporary scaffolding and everolimus drug delivery. The resorption of the BVS potentially overcomes the limitations of metallic stents. There is limited data on its use in daily clinical practice, especially in acute coronary syndrome (ACS) patients and complex lesions. We assessed the safety and performance of ABSORB BVS implantation in a selected patient cohort comparable with "real world" situation.
**Methods:** All patients who had undergone percutaneous coronary intervention (PCI) with ABSORB BVS implantation in our centre between August 2012 and June 2013 were included in this registry. Clinical outcome were defined as cardiac death, myocardial infarction (MI), target vessel revascularization (TVR), target lesion ravascularization (TLR), scaffold thrombosis (ST), and major adverse cardiac event (MACE; composite of cardiac death, MI and TVR). In addition, Quanitative Coronary Analysis including angiographic success rate will be performed and available at TCT.
**Results:** A total of 117 patients (136 lesions) were treated with an ABSORB BVS. The indication for PCI was stable angina in 53 patients (45%), non ST-segment elevation acute coronary syndrome (NSTE-ACS) in 38 patients (33%), and ST-segment elevation myocardial infarction (STEMI), in the setting of primary PCI, in 20 patients (17%). In total 64% of the 136 lesions had type B2 or C ACC/AHA classification, including 9 chronic total occlusions, 2 left main, 4 ostial, 3 long (>50 mm) and 8 complex bifurcation lesions treated with Tryton bifurcation stent and BVS. At least 1 month follow-up was available in 94 patients (median follow up 54 days; Q1-Q3: 40-67). MACE occurred in 4 patients (4.2%). Two patients experienced MI due to subacute scaffold thrombosis and two patients needed target vessel revascularization, including one target lesion, due to recurrent angina pectoris.
**Conclusions:** In a patient population reflecting daily clinical practice, including high-risk lesions and high-risk patients, the ABSORB BVS had good short term results.

## TCT-431

### Angiographic Results of a novel Novolimus Eluting Bioresorbable Coronary Scaffold System (NEBCSS) for the treatment of single de-novo coronary artery lesions: 6 month Serial QCA analysis results from the pivotal, prospective, multicentre, DESolve NX Trial

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**Background:** By design, drug-eluting bioresorbable scaffolds have been developed as an alternative to metallic stents in order to provide temporary vascular scaffolding, prevent vessel recoil and inhibit late clinical events due to excessive neointimal hyperplasia formation including restenosis and lesion revascularization. The DESolve® bioresorbable scaffold (Elixir Medical Co., Sunnyvale, CA) is a novel device combining a PLLA-based scaffold coated with a bioresorbable polylactide-based polymer and a potent anti-proliferative sirolimus metabolite Novolimus, with a drug dose of 5 mcg per mm of scaffold length. Our objective was to report serial QCA results from the prospective, non-randomized, single-arm multicentre DESolve Nx trial.
**Methods:** A total of 126 patients/lesions were enrolled in 13 sites in Europe, New Zealand and Brazil. Lesion criteria were single de novo lesion <14 mm in length, located in native coronary vessels 2.75-3.50 mm in diameter, with stenosis between 50-90% and TIMI flow ≥2. The study device was available in 3.00, 3.25 and 3.50 mm in diameter and 14 and 18 mm in length. All patients were assigned to angiographic follow-up at 6 months. Quantitative coronary angiography (QCA) analysis was performed at an independent angiographic core laboratory.
**Results:** Overall, mean age was 62 years and 21% had diabetes. Target lesions were evenly distributed in LAD, LCx and RCA, and most lesions were classified as type B (71%) according to the ACC/AHA classification. During procedure, the study device was successfully implanted in 122/126 cases (97%). Serial QCA results are shown in the Table.

| Variable | Preprocedure | Postprocedure* | 6-Month Follow-up* |
|---|---|---|---|
| N | 126 | 126 | 113 |
| Lesion length, mm | 11.20±3.77 | - | - |
| Reference diameter, mm | 3.06±0.31 | 3.09±0.26 | 3.01±0.29 |
| MLD, mm | 0.92±0.40 | 2.67±0.28 | 2.45±0.44 |
| % DS | 69.9±12.3 | 13.5±7.8 | 18.3±13.6 |
| Acute gain, mm | - | 1.73±0.45 | - |
| % acute recoil, mm | - | 6.6±6.2 | - |
| Late lumen loss, mm | - | - | 0.21±0.34 |

*In-scaffold

**Conclusions:** Angiographic results of the novel DESolve bioresorbable scaffold showed promising results in de novo coronary artery lesions including relatively low in-scaffold late lumen loss, a surrogate of neointimal hyperplasia, at 6-month follow-up.

## TCT-432

### Bioresorbable Vascular Scaffolds in Complex Coronary Lesions

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**Background:** The use of bioresorbable vascular scaffolds (BVS) has largely been restricted to simple lesions with a relatively small number of patients treated with complex lesions. The aim of this study was to evaluate the device success and short-term clinical outcomes of BVS in 'real world' patients including those with complex coronary lesions.
**Methods:** All consecutive patients treated with BVS between May 2012 and June 2013 at 2 centers were included in this analysis.
**Results:** A total of 123 lesions in 82 patients (87.8% male, mean age 64.6 years) were treated with BVS. Complex lesions were distributed as follows: long lesion >20mm (n=83), bifurcation lesions (n=49), calcified lesions (n=42), chronic total occlusions (n=9) and in-stent restenoses (n=7), one feature could be present in more than one lesion. Intracoronary vascular ultrasound and optical computed tomography were used in 85.4% and 20.3% of cases, respectively. Pre-dilation was performed in 98.4%, while post-dilation (mean 21.5 atmosphere) was utilized in all cases. Rotablation or scoring balloon was used in 22.0%. Device success was achieved in 99.2%. At median follow-up of 147